FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
STEPHEN S. RABINOWITZ
srabinowitz@friedfrank.com
RANDY C. EISENSMITH (*Pro Hac Vice*)
randy.eisensmith@friedfrank.com
ONE NEW YORK PLAZA
NEW YORK, NEW YORK 10004-1980
Telephone: 212.859.8000
Facsimile: 212.859.4000

DURIE TANGRI LLP
DARALYN J. DURIE (SBN 169825)
ddurie@durietangri.com
JOSHUA H. LERNER (SBN 220755)
jlerner@durietangri.com
GENEVIEVE P. ROSLOFF (SBN 258234)
grosloff@duritangri.com
217 Leisdesdorff Street
San Francisco, CA 94111
Telephone: 415-362-6666
Facsimile: 415-236-6300

Attorneys for Plaintiffs
GENENTECH, INC. and
ROCHE PALO ALTO LLC

DUANE MORRIS LLP
JESSICA E. LA LONDE (SBN 235744)
One Market Plaza, Suite 2200
San Francisco, CA 94105-1127
Telephone: +1 415 957 3000
Facsimile: +1 415 957 3001
E-mail:jelalonde@duanemorris.com

RICHARD T. RUZICH (pro hac vice)
ROBERT M. GOULD (pro hac vice)
190 South LaSalle Street, Suite 3700
Chicago, IL 60603-3433
Telephone: +1 312 499 6700
Facsimile: +1 312 499 6701
E-mail:rtruzich@duanemorris.com
rmgould@duanemorris.com

KERRY B. MCTIGUE (pro hac vice)
505 9th Street N.W., Suite 1000
Washington, D.C. 20004-2166
Telephone: +1 202 776 7800
Facsimile: +1 202 776 7801
E-mail:kbmctigue@duanemorris.com

VINCENT L. CAPUANO (pro hac vice)
LAURA A. VOGEL (pro hac vice)
470 Atlantic Ave., Suite 500
Boston, MA 02210
Telephone +1 857 488-4200
Facsimile +1 857 488-4201
E-mail vcapuano@duanemorris.com
lavogel@duanemorris.com

Attorneys for Defendant
SANDOZ INC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO

GENENTECH, INC. and ROCHE PALO ALTO LLC,

Plaintiff,

v.

SANDOZ INC.

Defendant.

Case No. 3:11-cv-01925-JSW
Related Case No. 3:11-cv-02410-JSW

JOINT CASE MANAGEMENT STATEMENT PURSUANT TO FED. R. CIV. P. 26(F) AND CIVIL LOCAL RULE 16-9

Date: July 29, 2011
Time: 1:30 p.m.
Judge: Honorable Jeffrey S. White

PARTIES' JOINT RULE 26(f) REPORT

Pursuant to Rule 26(f) of the Federal Rules of Civil Procedure, Civil Local Rule 16-9(a) and the Court's Standing Orders, Plaintiffs Genentech, Inc. ("Genentech") and Roche Palo Alto LLC ("Roche Palo Alto") and Defendant Sandoz Inc. ("Sandoz"), parties to the above-entitled action, upon conferring, submit the following report.

I. JURISDICTION AND SERVICE

This action arises under the Patent Act of 1952, as amended, 35 U.S.C. §§ 1-376. This Court has subject matter to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202. There is no dispute as to personal jurisdiction or venue, and all parties have been served.

II. FACTS

A. Plaintiff's Brief Description of the Case

This is a Hatch-Waxman action in which Plaintiffs assert that Sandoz infringed U.S. Patent No. 6,083,953 ("the '953 patent") under 35 U.S.C. § 271(e)(2) by filing Abbreviated New Drug Application ("ANDA") No. 202575 with a Paragraph IV Certification seeking approval to market generic valganciclovir hydrochloride 450 mg tablets (the "Sandoz Generic Product") prior to the expiration of the '953 patent. The claims of the '953 patent are directed to "the compound valganciclovir hydrochloride in crystalline form," pharmaceutical compositions comprising this compound, and methods of treatment comprising administering this compound. Plaintiffs contend that even if Sandoz's generic valganciclovir hydrochloride tablets are devoid of crystalline valganciclovir hydrochloride when initially sold (as Sandoz contends), the valganciclovir hydrochloride active ingredient will convert to crystalline form at least during use by patients, e.g., upon exposure to ambient atmospheric humidity during storage in pill trays. Accordingly, Plaintiffs contend that Sandoz's commercial manufacture, use, offer for sale and sale of the Sandoz Generic Product would infringe the '953 patent at least under 35 U.S.C. §§ 271(b) and (c) by inducing or contributing to infringement of the '953 patent by patients or others.

Plaintiffs will raise at least the following factual issues in the present case:

Whether Sandoz has infringed the '953 patent by submitting ANDA No. 202575;

Whether Sandoz's commercial use, offer for sale and sale of the Sandoz Generic

Product will infringe the '953 patent.

B. Sandoz's Brief Description of the Case

This a patent infringement and invalidity action concerning the '953 patent. Pursuant to the Hatch-Waxman Act, Plaintiffs have listed the '953 patent in the FDA's Orange Book for the drug product Valcyte®, and Sandoz has submitted an Abbreviated New Drug Application for Valcyte® with a paragraph IV certification that the '953 patent is either invalid, unenforceable, and/or will not be infringed by Sandoz's proposed generic drug product.

The '953 patent claims the compound valganciclovir hydrochloride "in crystalline form." Sandoz has informed Plaintiffs that the valganciclovir hydrochloride present in Sandoz's generic product is an amorphous material, and is not in crystalline form. Plaintiffs describe this case as one in which it will try to prove infringement by showing that the valganciclovir hydrochloride in Sandoz's product will convert to the claimed crystalline form. Sandoz contends that the claims of the '953 patent do not encompass material that converts to the crystalline form, and even if they did, Plaintiffs cannot prove that such conversion occurs in Sandoz's drug product.

Sandoz contends that the claims of the '953 patent are invalid for failure to comply with one or more provision of Title 35 of the United States Code, including, but not limited to, §§101, 102, 103 and/or 112.

Sandoz will raise at least the following factual issues in the present case related to the invalidity of the claims of the '953 patent: the level of skill in the art, the scope and content of the prior art and the differences between the claims of the '953 patent and the teachings of the prior art.

Sandoz will raise factual issues disputing Plaintiffs' allegations that Sandoz has infringed the '953 patent by (i) submitting ANDA No. 202575 and (ii) Sandoz's potential commercial use, offer for sale and sale of the Sandoz Generic Product.

III. LEGAL ISSUES

A. Plaintiffs' Statement of Legal Issues in Dispute

Plaintiffs will raise at least the following legal issues in the present case:

The construction of disputed terms of the asserted claims of the '953 patent.

B. Sandoz's Statement of Legal Issues in Dispute

Sandoz will raise at least the following legal issues in the present case:

(1) the construction of disputed terms of the asserted claims of the '953 patent;

(2) the invalidity of the '953 patent pursuant to 35 U.S.C. §§ 102, 103, and/or 112; and

(3) prosecution disclaimer and/or prosecution history estoppel as applied to the prosecution of the '953 patent.

IV. MOTIONS

There are no motions pending or anticipated at the present time.

V. AMENDMENT OF PLEADINGS

The parties propose that the deadline for filing any motion to amend the pleadings as set forth in Exhibit A. No such motion is pending at present.

VI. EVIDENCE PRESERVATION

The parties represent that they have taken appropriate steps to preserve evidence relevant to the issues reasonably evident in this action, including evidence in electronic form.

VII. DISCLOSURES

The parties have agreed to exchange their initial disclosures pursuant to Fed. R. Civ. P. 26(a) by August 12, 2011.

VIII. DISCOVERY

No discovery has yet been produced in this case. The parties conducted their Rule 26(f) conference on July 7, July 21 and July 22, 2011. The parties have agreed to abide by the default numbers of interrogatories and depositions provided under the Federal Rules of Civil Procedure.

A. Plaintiffs' Position Of the Scope Of Discovery

This case will require extensive discovery and analysis of both technical documents and physical materials that Plaintiffs will obtain in discovery from Sandoz. Sandoz will have the benefit of discovery taken in Hatch-Waxman actions previously filed in the District of New Jersey and the District of Delaware that involve the same patent-in-suit (see Section IX, *infra*.), in which the defendants asserted defenses and counterclaims of alleged patent invalidity, as Sandoz does here. Plaintiffs, on the other hand, bear the burden of proving infringement by the Sandoz Product – a

formulation that has never previously existed, is not publicly available, and is distinct from the accused products at issue in the New Jersey and Delaware litigations. Sandoz declined to provide Plaintiffs with samples of its generic product for testing prior to commencement of this litigation. In order to satisfy their burden of proving infringement, Plaintiffs will require access to technical documentation in possession of Sandoz, including at least ANDA No. 202785, any associated correspondence between Sandoz and the FDA, and any Drug Master Files relied on by Sandoz in connection with that ANDA. Plaintiffs will also need to obtain physical samples relating to the Sandoz Generic Product (including the active ingredient and the finished product) for scientific testing in order to determine whether the valganciclovir hydrochloride active ingredient will comprise or convert to crystalline form over time during use by patients, e.g. when the tablets are exposed to ambient atmospheric humidity during storage in pill trays.

B. Sandoz's Position On the Scope of Discovery

Sandoz believes that this case will involve significantly less discovery than the extensive discovery proposed by Plaintiffs. This case concerns just one patent and will require limited fact discovery on Sandoz's product. The parties will also require expert discovery on issues of infringement and invalidity. Plaintiffs have previously asserted the '953 patent against two other pharmaceutical companies proposing to manufacture generic valganciclovir hydrochloride tablets, Ranbaxy Laboratories and Endo Pharmaceuticals. Roche Palo Alto LLC v. Ranbaxy Laboratories Ltd. No. 06-2003 (D.N.J.) and Roche Palo Alto LLC v. Endo Pharmaceuticals, Inc., No. 10-cv-00261-GMS (D. Del.).

Extensive discovery on the invalidity of the '953 patent has already taken place in these cases: Sandoz does not believe that considerable additional fact discovery on the '953 patent should be necessary for its invalidity case provided that it receives access to the discovery that has already taken place in these prior actions. Sandoz's invalidity case will require discovery and analysis of technical documents (research reports, laboratory notebooks, related patent applications, and prosecution file histories) to be obtained from Plaintiffs, including Plaintiffs' NDA. Sandoz will also require Plaintiffs to produce documents related to the sales and marketing of Valcyte®, as well as documents related to comparison of Valcyte to other drug products, in order to counter any

proffered information from Plaintiffs concerning non-obviousness. Sandoz expects that many of Plaintiffs' documents relevant to Sandoz's invalidity case were produced in the previous Ranbaxy and Endo actions and should be ready to produce to Sandoz.

IX. RELATED CASES

Pursuant to an Order dated June 17, 2011, this case is related to *Genentech, Inc. v. Apotex, Inc.*, No. 11-cv-02410-JSW, presently pending before this Court. Plaintiffs submit, and Sandoz does not oppose, that this case should be consolidated with the related *Genentech v. Apotex* case for pretrial purposes and for trial. Apotex, Inc. agrees that these two cases should be consolidated for pretrial purposes, but has taken no position as yet on whether they should be consolidated for trial.

On March 31, 2010, Roche Palo Alto commenced a Hatch-Waxman patent infringement action against Endo Pharmaceuticals, Inc. in the District of Delaware in view of Endo's filing of an ANDA seeking approval to market generic valganciclovir hydrochloride 450 mg tablets, which ANDA included a Paragraph IV Certification against the '953 Patent. *Roche Palo Alto LLC v. Endo Pharmaceuticals, Inc.*, No. 10-cv-00261-GMS. That litigation is scheduled for a trial commencing on April 18, 2012.

On April 28, 2006, Roche Palo Alto commenced a Hatch-Waxman patent infringement action against Ranbaxy Laboratories Limited, et al., in the District of New Jersey in view of Ranbaxy's filing of an ANDA seeking approval to market generic valganciclovir hydrochloride 450 mg tablets, which ANDA included a Paragraph IV Certification against the '953 Patent. *Roche Palo Alto LLC v. Ranbaxy Laboratories Ltd.* No. 06-2003 (D.N.J.). An opinion was issued in that litigation on September 30, 2009 finding the claims of the '953 patent valid but not infringed by Ranbaxy's generic product. *Roche Palo Alto LLC v. Ranbaxy Labs. Ltd.*, No. 06-2003, 2009 US Dist. LEXIS 90804 (Sept. 30, 2009, D.N.J.) The parties subsequently settled, and on August 8, 2010, the court issued an order vacating the judgment and related orders and dismissing all claims and counterclaims with prejudice.

X. RELIEF

A. Plaintiffs' Statement

Plaintiffs pray that the Court

(1) declare, adjudge, and decree that Sandoz has infringed the '953 patent by submitting ANDA No. 202575;

(2) declare, adjudge, and decree that Sandoz's commercial use, offer for sale and sale of the Sandoz Generic Product will infringe the '953 patent;

(3) issue an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Sandoz Generic Product be no earlier than the expiration date of the '953 patent, or any later expiration of exclusivity to which Roche Palo Alto is or becomes entitled; and

(4) issue a permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) & 283 and 28 U.S.C. § 1331 restraining and enjoining Sandoz and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in commercial activity that would directly or indirectly infringe the '953 patent.

B. Sandoz's Statement

Sandoz asks the Court for the following relief:

Adjudge that Sandoz has not and will not infringe any patent asserted by Plaintiffs/Counterclaim Defendants;

Adjudge that no patent claims asserted by Plaintiffs/Counterclaim Defendants is valid;

Enjoin Plaintiffs/Counterclaim Defendants and their agents, etc., from threatening or initiating infringement litigation against Sandoz or its customers, etc. of the '953 patent

Grant Sandoz judgment in its favor on Plaintiffs' Complaint;

Deny Plaintiffs'/Counterclaim Defendants' request for injunctive relief;

Dismiss Plaintiffs'/Counterclaim Defendants' Complaint with prejudice;

Declare that the claims of the '953 patent are not and will not be infringed by Sandoz; and

Award any other such relief as is just and proper.

XI. SETTLEMENT AND ADR

The parties agree that ADR should take the form of direct settlement discussions between the parties.

XII. CONSENT TO MAGISTRATE JUDGE FOR ALL PURPOSES

A declination to proceed before a magistrate judge has been filed.

XIII. OTHER REFERENCES

The parties agree that this case is not suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

XIV. NARROWING OF ISSUES

The parties do not believe that the issues in dispute are amenable to narrowing at this time.

XV. PROPOSED SCHEDULE

The parties' respective proposals for the pretrial schedule are set forth in the table attached hereto as Exhibit A.

A. Plaintiffs' Statement

Sandoz proposes a fact discovery period (ending about 13 months after commencement of this action) that would deprive Plaintiffs of a full and fair opportunity to prepare their infringement case. Whereas Sandoz will have the benefit of discovery and briefing in two prior litigations that explored the same invalidity issues that Sandoz raises here, the Plaintiffs' infringement case involves a drug product that has never previously existed or been the subject of any prior litigation. Plaintiffs' infringement case will require analysis of large numbers of densely technical documents and on careful and exact scientific testing of physical samples to be obtained in discovery, in order to determine how the physical form of the active ingredient in the Sandoz Generic Product changes over time when exposed to the conditions that will be encountered during use by patients.

The two other Hatch-Waxman litigations referred to by Sandoz provided adequate time for fact discovery. In the *Ranbaxy* litigation, commenced in the District of New Jersey on April 28, 2006, fact discovery closed about **18 months** later on November 21, 2001. In the Endo litigation, commenced on March 31, 2010 in the District of Delaware, Chief Judge Sleet rejected the defendant's request for a truncated fact discovery period in view of the prior Ranbaxy litigation, and instead adopted a pretrial schedule under which fact discovery closes on August 26, 2011, about **17 months** after the action was commenced. In each of those litigations, the defendant provided samples relating to its proposed generic product for testing prior to commencement of the action

Here, Sandoz's refusal to provide samples prior to commencement of this litigation has delayed Plaintiffs' ability to commence its scientific testing. Plaintiffs are proposing a schedule that

provides for the close of fact discovery about 16 months after commencement of this action.

B. Sandoz's Statement

The fact discovery period Sandoz proposes is more than adequate for Plaintiffs to conduct the studies they propose with Sandoz's product. Under Sandoz's proposed schedule Plaintiffs will have until June 30, 2012 (the date for service of opening expert reports) to complete their proposed "pill tray" experiment - a study that takes just 5 weeks. Roche Palo Alto LLC v. Ranbaxy Labs. Ltd., No. 06-2003, 2009 US Dist. LEXIS 90804 (Sept. 30, 2009, D.N.J.).

Sandoz was under no obligation to provide samples of its product to Plaintiffs prior to commencement of this suit. Discovery in this case will begin in August 2011 and Sandoz expects Plaintiffs will request samples of Sandoz's product early in discovery. Putting aside that the claims of the '953 patent do not cover valganciclovir hydrochloride that converts to a "crystalline form," and that Plaintiffs proposed "pill tray" experiments are irrelevant to any claim in this case, Plaintiffs will be in possession of samples of Sandoz's product with ample time to conduct the 5-week "pill tray" experiment (multiple times if desired) and prepare its opening expert reports before June 30, 2012.

Plaintiffs proposal to extend the time needed to conduct these experiments for an extra 6 months (until Plaintiffs' December 31, 2012 proposed date for service of opening expert reports), as well as extension of all dates by 6 months, including a proposed trial date of May 2013, is an attempt to delay this case and ultimately delay competition from Sandoz.

XVI. SCHEDULING

The parties' respective proposals for the pretrial schedule are set forth in the table attached hereto as Exhibit 1.

A. Plaintiffs' Position

Since Plaintiffs have not yet had access to Sandoz's technical documents or to physical samples relating to Sandoz Generic Product for testing, and since the Local Patent Rules set forth a deadline for infringement contentions that will pass before Plaintiffs will be able to conduct the necessary analysis and testing, Plaintiffs have no choice but to submit their infringement contentions initially on information and belief and to supplement them in light of their scientific analysis of the

materials to be obtained in discovery. Plaintiffs respectfully submit that information from analysis and testing of documents and physical samples obtained in discovery would constitute good cause to supplement Plaintiffs' infringement contentions.

B. Sandoz's position

Sandoz proposes that the Court consider whether good cause is shown for supplementing any submission under the Local Patent Rules at the time a request for supplementation is made.

XVII TRIAL

This case will be tried to the Court. The parties preliminarily anticipate that any trial will be 10 court days.

XVIII. DISCLOSURE OF NON-PARTY INTERESTED ENTITIES OR PERSONS

A. Plaintiffs' Statement

The following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations), or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding or (ii) have a nonfinancial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding:

Genentech, Inc., Roche Palo Alto LLC, and Hoffmann-La Roche Inc. are all wholly-owned subsidiaries of Roche Holdings, Inc. Roche Holdings, Inc. (a Delaware corporation) is a wholly-owned subsidiary of Roche Finance Ltd. Roche Finance Ltd (a Swiss company) is a wholly-owned subsidiary of Roche Holding Ltd (a Swiss company), which has no parent corporation. Upon information and belief, Novartis AG as economic beneficiary and its subsidiary Novartis International Ltd, as direct holder, both in Basel, Switzerland, hold 53,332,863 shares of Roche Holding Ltd, which constitutes less than approximately 33.3% of Roche Holding Ltd's voting shares.

B. Sandoz's Statement

On April 28, 2011, Sandoz filed the "Certification of Interested Parties" required by Civil Local Rule 3-16. This Certification stated as follows: "Pursuant to Fed. R. Civ. P. 7.1 and Civil L.R. 3-16, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial

interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding: Novartis AG is the ultimate parent company of Sandoz Inc., owning 100% of Sandoz Inc. and trading on the New York Stock Exchange under the ticker symbol NVS."

Dated: July 22, 2011

STEPHEN S. RABINOWITZ
RANDY C. EISENSMITH
FRIED, FRANK, HARRIS, SHRIVER
& JACOBSON LLP

DARALYN J. DURIE
JOSHUA H. LERNER
GENEVIEVE P. ROSLOFF
DURIE TANGRI LLP

By: */s/ Joshua H. Lerner*
JOSHUA H. LERNER

Attorneys for Plaintiffs
GENENTECH, INC. and
ROCHE PALO ALTO LLC

Dated: July 22, 2011

By: */s/ Jessica E. La Londe*

DUANE MORRIS LLP

JESSICA E. LA LONDE
RICHARD T. RUZICH
ROBERT M. GOULD
KERRY B. MCTIGUE
VINCENT L. CAPUANO
LAURA A. VOGEL

Attorneys for Defendant
SANDOZ INC.

Attestation

I, Joshua H. Lerner, am the ECF User whose identification and password are being used to file this document. Pursuant to General Order 45.X.B, I hereby attest that counsel for Defendant Apotex, Inc. has concurred in this filing.

/s/ Joshua H. Lerner
Joshua H. Lerner

EXHIBIT A

EVENT	Plaintiffs' proposed date	Defendant's proposed date
Rule 26(a) Initial Disclosures	August 12, 2011	
Disclosure of Asserted Claims and Infringement Contentions and Accompanying Document Production (Patent L.R. 3-1 & 3-2)	August 12, 2011	
Invalidity Contentions and Accompanying Production (Patent L.R. 3-3 & 3-4)	September 26, 2011	
Exchange of Proposed Terms for Construction (Patent L.R. 4-1	October 10, 2011	
Exchange of Preliminary Claim Construction and Extrinsic Evidence (Patent L.R. 4-2)	October 31, 2011	
Joint Claim Construction and Prehearing Statement (Patent L.R. 4-3)	November 28, 2011	
Completion of Claim Construction Discovery (Patent L.R. 4-4)	December 18, 2011	
Opening Claim Construction Brief (Patent L.R. 4-5(a))	January 12, 2012	
Responsive Claim Construction Brief (Patent L.R. 4-5(b))	January 26, 2012	
Reply Claim Construction Brief (Patent L.R. 4-5(c))	February 2, 2012	
Claim Construction Hearing (Patent L.R. 4-6)	February 16, 2012 (subject to the convenience of the Court)	
Disclosure of Advice of Counsel (Patent L.R. 3-7)	50 days after Court issues its claim construction ruling	
Joinder of Parties and Amendment of Pleadings	December 15, 2011	
Close of Fact Discovery	August 28, 2012	May 31, 2012
Opening Expert Reports	September 28, 2012	June 30, 2012

EVENT	Plaintiffs' proposed date	Defendant's proposed date
Rebuttal Expert Reports	October 29, 2012	July 31, 2012
Close of Expert Discovery	November 29, 2012	August 31, 2012
Summary Judgment Motions Filed	No later than December, 2012	No later than September 15, 2012
Plaintiff's Proposed Pretrial Order	January 11, 2013	October 1, 2012
Defendant's Comments on Proposed Pretrial Order	January 25, 2013	October 14, 2012
Submission of Joint Pretrial Order to Court	February 1, 2013	October 21, 2012
Deadline for Motions in Limine	January 11, 2013	October 1, 2012
Due date for responses to Motions in Limine	January 25, 2013	October 14, 2012
Due date for reply re Motions in Limine	February 1, 2013	October 21, 2012
Pretrial Conference	February, 2013 (subject to the convenience of the Court)	October 2012 (subject to the convenience of the Court)
Trial	February, 2013 (subject to the convenience of the Court)	November 2012 (subject to the convenience of the Court)